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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,305	09/13/2000	Takaaki Sato	P19977	7747

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EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,305

Applicant(s)

SATO ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Claim 6 **remain rejected** for the reasons set forth at page 2 of the Office Action mailed on 07-03-2002 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant argues that the instant invention is drawn to screening method and an agent used in the screening method. However, claim 6 is not limited to reagents used in screening method but is drawn to "a medicament" for the purpose stated in the preamble, i.e., treatment and prevention of disease. The specification does not teach how to make the instantly claimed product and how to use the product. *cancelled*

Claim Rejections - 35 USC § 112

Claims 5 and 6 are rejected under for the reasons set forth in the two previous Office Action 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant argues that the instant claims are drawn to screening method but claims 5 and 6 require "medicament" applicant has been screened yet and since applicant does not describe what it is, it would take undue experimentation to figure out make it and how to use it.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, and 6 say that "medicament for...diagnosis" and it is not clear how a medicament is used for diagnosis, therefore confusing and indefinite. *moot*

Claim 3 recites "interaction" but it is not clear what the metes and bounds are for the limitation. *maintain*

Claim 5 is confusing because the claim is drawn to screening of a medicament and but the active step says the screening assay is performed in presence of yet unscreened medicament. *amended.*

Claim 2 recites "Huntingtin" but it is not clear what the metes and bounds are for the limitation. For the purpose of this office action, this examiner will assume the limitation means Huntington. However, this treatment does not relieve applicant the burden of responding to this office action.

Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a contacting step in which the reaction of the sample with the reagents necessary for the assay, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay.

Claim 7 recites "pharmacological action of a NADE-apoptosis related complex" but it is not clear what the metes and bounds are for the limitation. *can be added*

Claim 7 recites the limitation "the pharmacological action" in line 3. There is insufficient antecedent basis for this limitation in the claim. *can be added*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. Claim 6 is interpreted as drawn to a product for treatment, prevention, and/or diagnosis of apoptosis-associated disease. The specification teaches method of screening medicament by the instantly claimed method of claim 3 but the specification does not teach that applicant had possession of a medicament screened by the method of instant claim 3 and also able to accomplish the purpose stated in the preamble of the claim. The specification does not teach how to make the instantly claimed medicament and the specification does not teach the molecular structure of the medicament.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Garkavtsev et al (IDS, 1998, Nature vol. 391, pages 295-298), Ichimura et al (IDS, 1988, Proc. Natl. Acad. Sci. USA. Vol. 85, pages 7084-8), Imataka et al (IDS, 1998, EMBO J. vol. 17, pages 7480-7489), Kalchman et al (IDS, 1997, Nature Genetics vol. 16, pages 44-53), or Su et al (IDS, 1997, EMBO J vol. 16, pages 1279-90).

Claim 1 is broadly drawn generic product claim and claim 2 is drawn to species (i.e., P33 ING relative protein, 14-3-3 protein, eIF4G, Huntington-binding protein 1, NIK/HGK protein) that belong to generic claim 1.

Garkavtsev et al teach P33 ING relative protein; Ichimura et al teach 14-3-3 protein; Imataka et al teach eIF4G; Kalchman et al teach Huntington-binding protein 1; Su et al teach NIK/HGK protein.

Thus, Garkavtsev et al (IDS, 1998, Nature vol. 391, pages 295-298), Ichimura et al (IDS, 1988, Proc. Natl. Acad. Sci. USA. Vol. 85, pages 7084-8), Imataka et al (IDS, 1998, EMBO J. vol. 17, pages 7480-7489), Kalchman et al (IDS, 1997, Nature Genetics vol. 16, pages 44-53), or Su et al (IDS, 1997, EMBO J vol. 16, pages 1279-90) anticipate the instant claims.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: A method for screening a medically useful candidate compound using NADE and NADE-binding partners listed in claims 1 and 2 are novel and does not require undue experimentation. The claims would better define the invention if the active steps of claim 5 were written into claim 1, thereby changing claim 1 to method claim instead of product claim, but substituting "a candidate" for "medicament", or "candidate compound" would be better if the specification has support for "candidate compound". If applicant chooses to use the limitation "candidate compound" instead of "medicament, applicant is requested to point out the support for the limitation. Also substituting "interacts" for "binds" would be better since the specification does not describe any other interaction and then cancel claim 5 as redundant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
December 12, 2002

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
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1600